

Docket No.: 14514-00007-US1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
David Needham

Application No.: 10/083,734

Confirmation No.: 3807

Filed: February 26, 2002

Art Unit: 1615

For: Temperature-Sensitive Liposomal Formulation

Examiner: G. S. Kishore

PETITION UNDER 37 CFR §1.182 TO WITHDRAW TERMINAL DISCLAIMERS

MS Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant requests that the terminal disclaimers filed in this application on June 21, 2004 and May 16, 2008 be withdrawn.

Terminal disclaimer of June 21, 2004

Applicant requests that the terminal disclaimer filed on June 21, 2004, disclaiming the terminal part of the statutory term of any patent granted on this application which would extend past the expiration date of the full statutory term of United States patent number 6,200,598, be withdrawn.

This terminal disclaimer was filed in response to a double patenting rejection made in the Office Action mailed December 17, 2003, in which the Examiner stated:

15. Claims 38-42 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 and 24 of U.S. Patent No. 6,200,598. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic

claims include the specific components and the ratios recited in the claims of said patent.

Office Action, page 8.

Independent claims 38 and 65 pending at the time of the rejection read as follows:

38. A liposome containing an active agent, said liposome having a gel-phase lipid bilayer membrane comprising phospholipid and a second component, wherein phospholipids are the primary lipid source for the lipid bilayer membrane and wherein said second component is contained in the bilayer membrane in an amount sufficient to increase the percentage of material to be released at the phase transition temperature of the lipid bilayer, compared to that which would occur in the absence of the second component, and wherein the second component is present in the lipid bilayer membrane such that the membrane is stable in the gel-phase, said material to be released from the liposome being the second component or a third component which is entrapped within the liposome interior or associated with the lipid bilayer membrane.

65. A liposome containing an active agent, said liposome having a solid-phase membrane comprising a membrane-forming material and a surface active agent, wherein surface active agent is contained in the bilayer membrane in an amount sufficient to increase the percentage of active agent released at the phase transition temperature of the solid-phase membrane, compared to that which would occur in the absence of said surface active agent, and wherein the surface active agent is present in the membrane so as to not destabilize the membrane while the membrane is in the solid phase.

In an amendment filed at the same time as the terminal disclaimer, all of the claims rejected for obviousness-type double patenting were canceled and claim 38 was rewritten as claim 66. The examiner does not appear to have considered whether the rejection made against claim 38 applied to the rewritten claim 66. Claim 66 was subsequently canceled in an amendment dated February 26, 2008.

The independent claim now pending in this application are claims 176 and 183 which read as follows:

176. A liposome having a gel-phase bilayer membrane, comprising:

an active agent selected from the group consisting of a pharmacologically active agent, a therapeutic agent, a flavor agent, a diagnostic or imaging agent, a nutritional agent, and combinations thereof,

wherein the gel-phase bilayer has a phase transition temperature of 39 to 45°C, and wherein the gel-phase lipid bilayer membrane comprises:

- (a) a first component which is dipalmitoylphosphatidylcholine (DPPC) in an amount ranging from 80 to 98 mol %; and
- (b) a second component selected from the group consisting of monostearoylphosphatidylcholine (MSPC) and monopalmitoylphosphatidylcholine (MPPC) in an amount ranging from 2 to 20 mol%.

183. A liposome having a gel-phase bilayer membrane, comprising:

an active agent selected from the group consisting of a pharmacologically active agent, a therapeutic agent, a flavor agent, a diagnostic or imaging agent, a nutritional agent, and combinations thereof,

wherein the gel-phase bilayer has a phase transition temperature of 39 to 45°C, and wherein the gel-phase lipid bilayer membrane comprises:

- (a) a first component which is dipalmitoylphosphatidylcholine (DPPC) in an amount ranging from 80 to 98 mol %; and
- (b) a second component selected from the group consisting of:
 - (i) monostearoylphosphatidylcholine (MSPC) and 1,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-[poly(ethyleneglycol) 2000] (DSPE-PEG-2000) in an amount ranging from 2 to 20 mol%; and
 - (ii) monopalmitoylphosphatidylcholine (MPPC) and 1,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-[poly(ethyleneglycol) 2000] (DSPE-PEG-2000) in an amount ranging from 2 to 20 mol%.

It is readily apparent that the claims that are currently pending in the application are dramatically different from those rejected for obviousness-type double patenting. Further, the

currently pending claims were not subject to the rejection that occasioned filing of the terminal disclaimer.

MPEP §1490 (VII) states “[i]f timely requested, a recorded terminal disclaimer may be withdrawn before the application in which it is filed issues as a patent, or in a reexamination proceeding, before the reexamination certificate issues.” Since the present application has not issued as a patent, Applicant submits that this request is timely and requests withdrawal of this terminal disclaimer.

Terminal disclaimer of May 16, 2008

Applicant requests that the terminal disclaimer filed on May 16, 2008, disclaiming the terminal part of the statutory term of any patent granted on this application which would extend past the expiration date of the full statutory term of United States patent number 6,726,925, be withdrawn. This terminal disclaimer was submitted in response to the obviousness-type double patenting rejection made in the Office Action of April 28, 2008. In the Office Action, the Examiner stated:

Claims 176-1 89 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 and 42-68 of U.S. Patent No. 6,726,925. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant claims and patented claims are drawn to same liposomal compositions. Patented claims are generic with respect to the phospholipids and their amounts and therefore, instant claims reciting specific phospholipids are deemed to be anticipated by the patented claims.

Applicant respectfully submits that rejection was improper as applied to the pending claims and should not have been made.

MPEP §804 (B)(I) states “[a] nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is *either anticipated by, or would have been obvious over*, the reference claim(s).” Citations omitted, emphasis added.

Thus, in order to be a proper rejection, the claims in the present application must be anticipated by, or obvious over, the cited claims of United States patent no. 6,726,925. Applicant submits the presently pending claims are neither anticipated by nor obvious over the cited patent claims.

The examiner stated that the claims of United States patent no. 6,726,925 are generic and, therefore, anticipate the present claims. Applicant respectfully disagrees.

As noted in MPEP §2131.02 “A genus does not always anticipate a claim to a species within the genus.” Further, “[w]hen the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives . . . anticipation can only be found if the classes of substituents are sufficiently limited or well delineated.” *Id.* The genus claims of United States patent no. 6,726,925 are extremely broad and encompass a huge variety of compositions. For example, independent claim 1 reads:

1. A liposome, comprising a gel-phase lipid bilayer membrane having a phase transition temperature, and an active agent, wherein the gel-phase lipid bilayer membrane comprises:

- (a) one or more phospholipids selected from the group consisting of phosphatidyl cholines, phosphatidyl glycerols, phosphatidyl inositols, and phosphatidyl ethanolamines, wherein the one or more phospholipids have two acyl groups; and
- (b) one or more lysolipids selected from the group consisting of monoacylphosphatidyl cholines, monoacylphosphatidylglycerols, monoacylphosphatidylinositols, and monoacylphosphatidylethanolamines,

wherein the one or more lysolipids have one acyl group; and wherein the active agent is selected from the group consisting of a pharmacologically active agent or a diagnostic agent; and wherein the phase transition temperature is 39 to 45°C., and, wherein the amount of the one or more lysolipids in the gel-phase lipid bilayer membrane is sufficient to increase a first percentage of active agent released from the liposome at the phase transition temperature, compared to a second percentage of active agent released in the absence of the one or more lysolipids.

The test for whether a genus anticipates a species is whether one of ordinary skill in the art is able to "at once envisage" the species. See MPEP § 2131.02. Applicant respectfully submits that one of ordinary skill in the art, upon inspection of the genus claim of United States patent no. 6,726,925, would not immediately envisage the species claimed in the present application and, therefore, the present claims are not anticipated by the genus claims of United States patent no. 6,726,925.

MPEP § 2144.08 sets forth the requirements for finding a subgenus or species of chemical compound obvious in view of a disclosed genus. After making the required determination of the *Graham* factors (*Graham v. John Deere*, 383 U.S. 1, 17 (1966)) the examiner is directed to determine whether one of ordinary skill in the art would have been motivated to select the claimed species or subgenus by considering: (a) the size of the genus; (b) the express teachings; (c) the teachings of structural similarity; (d) the teachings of similar properties or uses; (e) the predictability of the technology; (f) any other teaching to support the selection of the species or subgenus. MPEP § 2144.08 (II)(A)(4a-f).

As discussed above, the genus claims of United States patent no. 6,726,925 represent a nearly limitless number of compositions. Given this huge number, the claims of the present application are not obvious over the genus claims of United States patent no. 6,726,925.

Since the present claims are neither anticipated by, nor obvious over, the claims of United States patent no. 6,726,925, the obviousness-type double patenting rejection was improper and should not have been made. Accordingly, Applicant request withdrawal of the terminal disclaimer filed May 16, 2008.

This petition is submitted with the petition fee of \$400 specified in 37 CFR § 1.17(f). Applicant believes no other fee is due with this submission. However, the Commissioner is hereby authorized in this, concurrent, and further submissions, to charge payment or credit any overpayment to Deposit Account No. 22-0185, under Order No. 14514-00007-US1 from which the undersigned is authorized to draw.

Dated: October 3, 2008

Respectfully submitted,

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